

Docket No. 44657-AAA-PCT-US/JPW/GJG/DNS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Joseph R. Berger  
Serial No.: 10/052,961                      Group Art Unit: 1617  
Filed : January 18, 2002              Examiner: Russell Travers  
Title : A METHOD FOR AMELIORATING MUSCLE WEAKNESS/WASTING  
IN A PATIENT INFECTED WITH HUMAN IMMUNODEFICIENCY  
VIRUS-TYPE 1

1185 Avenue of the Americas  
New York, New York 10036  
May 14, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TO THE  
ACCOMPANYING REQUEST FOR CONTINUED EXAMINATION (RCE) AND PETITION  
FOR ONE MONTH EXTENSION OF TIME**

Applicants are filing this Third Supplemental Information Disclosure Statement and petition for a one-month extension of time to bring the subject application into pending status on the date of filing of the accompanying Request for Continued Examination. Specifically, a response to the January 14, 2004 Final Office Action was due April 14, 2004. Applicants hereby request a one-month extension of time. With a one-month extension of time, a response to the January 14, 2004 Final Office Action is due May 14, 2004. The fee for a one-month extension of time is \$55.00, and a check including this amount is enclosed. Therefore, a response to the January 14, 2004 Office Action is now due May 14, 2004 and the accompanying Request for Continued Examination is being timely filed.

Applicants are filing this Third Supplemental Information Disclosure Statement to supplement the Information Disclosure Statement filed on January 18, 2002, the Supplemental Information Disclosure Statement filed on October 9, 2003, and the Supplemental

Applicant : Joseph R. Berger  
Serial No. : 10/052,961  
Filed : January 18, 2002  
Page 2

Information Disclosure Statement filed on March 5, 2004.

In accordance with their duty of disclosure under 37 C.F.R. § 1.56 and pursuant to § 1.97(b)(4), applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit A**) and attached hereto:

1. U.S. Patent No. 5,872,147, issued February 16, 1999, Bowen (**Exhibit 1**);
2. U.S. Patent No. 6,576,659, issued June 10, 2003, Fishbein (**Exhibit 2**);
3. U.S. Patent No. 6,670,351, issued December 30, 2003, Berger (**Exhibit 3**);
4. U.S. Patent Application Publication No. 2002/0091155, Published July 11, 2002, Berger (**Exhibit 4**);
5. U.S. Patent Application Publication No. 2003/0049716, Published March 13, 2003, Barton and Kramer. (**Exhibit 5**);
6. U.S. Serial No. 10/799,264, filed March 12, 2004, Fishbein (**Exhibit 6**);
7. U.S. Serial No. 10/799,197, filed March 12, 2004, Fishbein (**Exhibit 7**);
8. *Chicago Tribune*, (Sep. 20, 1991), North Sports Final edition, Business Section, page 1 (**Exhibit 8**);
9. Demling and DeSanti, (1997), "Oxandrolone, an Anabolic Steroid, Significantly Increases the Rate of Weight Gain In the Recovery Phase After Major Burns," *J. Trauma*, Vol. 43, No. 1, pp. 47-51 (**Exhibit 9**);

Applicant : Joseph R. Berger  
Serial No. : 10/052,961  
Filed : January 18, 2002  
Page 3

10. Demling and De Santi, (October 1998), "Closure of the 'Non-Healing Wound' Corresponds with Correction of Weight Loss Using the Anabolic Agent Oxandrolone," *Ostomy/Wound Management*, Vol. 44, No. 10, pp. 58-60, 62, 64, 66, 68 (**Exhibit 10**);
11. Demling, (1999), "Comparison of the Anabolic Effects and Complications of Human Growth Hormone and the Testosterone Analog, Oxandrolone, After Severe Burn Injury," *Burns*, Vol. 25, pp. 215-221 (**Exhibit 11**);
12. Demling, (Mar-Apr 2000), "Oxandrolone, an Anabolic Steroid, Enhances the Healing of a Cutaneous Wound in the Rat," *Wound Repair Regen.*, Vol. 8, No. 2, pp. 97-102 (**Exhibit 12**);
13. Demling and DeSanti, (2001), "The Rate of Restoration of Body Weight After Burn Injury, Using the Anabolic Agent Oxandrolone, is not Age Dependent," *Burns*, Vol. 17, pp. 46-51, (**Exhibit 13**);
14. Demling and DeSanti, (September/October 2001), "The Anabolic Steroid, Oxandrolone, Reverses the Wound Healing Impairment in Corticosteroid-Dependent Burn and Wound Patients," *Wounds*, Vol. 13, No. 5, pp. 203-207 (**Exhibit 14**);
15. DeSanti et al., (1998), "Development of a Burn Rehabilitation Unit: Impact on Burn Center Length of Stay and Functional Outcome," *Journal of Burn Care & Rehabilitation*, Vol. 19, No. 5, pp. 414-419 (**Exhibit 15**);
16. Ehrlich and Hunt, (August 1969), "The Effects of Cortisone and Anabolic Steroids on the Tensile Strength of Healing Wounds," *Ann Surg.*, Vol. 170, No. 2, pp. 203-206 (**Exhibit 16**);

Applicant : Joseph R. Berger  
Serial No. : 10/052,961  
Filed : January 18, 2002  
Page 4

17. Eisenberg, (1966), 65 *Chemical Abstracts*:40387 (**Exhibit 17**);
18. Eisenberg, (May 1966), "Effects of Androgens, Estrogens and Corticoids on Strontium Kinetics in Man," *J. Clin. Endocr.*, Vol. 26, pp. 566-572 (**Exhibit 18**);
19. Ferraresi, (April 1996), "Clinical Profile of Oxandrin," BTG Pharmaceuticals (**Exhibit 19**);
20. Grant, (1980), "Patient Selection," in *Handbook of Total Parenteral Nutrition*, Saunders, pp. 7-46 (**Exhibit 20**);
21. Hausmann et al., (March/April 1990), "Anabolic Steroids In Polytrauma Patients. Influence on Renal Nitrogen and Amino Acid Losses: A Double Blind Study," *J. Parent. Enteral. Nutr.*, Vol. 14, No. 2, pp. 111-114 (**Exhibit 21**);
22. Helfman and Falanga, (August 1995), "Stanozolol as a Novel Therapeutic Agent in Dermatology," *J. of the American Acad. of Dermatology*, Vol. 33, No. 2, pp. 254-258 (**Exhibit 22**);
23. Jekot and Purdy, (April 1993), "Treating HIV/AIDS Patients with Anabolic Steroids," *AIDS Patient Care*, pp. 68-74 (**Exhibit 23**);
24. Koehler et al., (1998), "Achieving Healing of 'Non-Healing Pressure Ulcers," 1998 WOCN 30<sup>th</sup> Annual Conference, p. 37 (**Exhibit 24**);
25. Kotler, (1996), "Dilemmas in the Treatment of Weight Loss," BTG Pharmaceuticals, pp. 1-7 (**Exhibit 25**);
26. Levien et al., (July 1994), "Reviews of Trimetrexate and Oxandrolone," *Hospital Pharmacy*, Vol. 29, No. 7, pp. 696-702, 705-708 (**Exhibit 26**);

Applicant : Joseph R. Berger  
Serial No. : 10/052,961  
Filed : January 18, 2002  
Page 5

27. Martindale, (1982), *The Extra Pharmacopoeia 28<sup>th</sup> edition*, The Pharmaceutical Press, London, Reynolds and Prasad Eds., p. 1430 (**Exhibit 27**);
28. PR Newswire, 0828P8715, (August 28, 1991), "Gynex Obtains International Rights to Drug to Treat For Growth Disorders, AIDS" (**Exhibit 28**);
29. Schwartz and Miller, (1986), "Androgens and Anabolic Steroids," in *Modern Pharmacology, Second Edition*, Little Brown and Company, Boston/Toronto, Craig and Stitzel Eds., pp. 905-924 (**Exhibit 29**);
30. Tennenbaum and Shklar, (December 1970), "The Effect of an Anabolic Steroid on the Healing of Experimental Extraction Wounds," *Oral Surg.*, Vol. 30, No. 6, pp. 824-834 (**Exhibit 30**); and
31. Udupa and Chansouria, (March 1969), "Studies on Wound Healing," *Indian J. Med. Res.*, Vol. 57, pp. 434-456 (**Exhibit 31**).

This Third Supplemental Information Disclosure Statement accompanies a Request for Continued Examination ("RCE") of U.S. Serial No. 10/052,961, filed January 18, 2002. A Final Office Action was issued January 14, 2004 in connection with the U.S. Serial No. 10/052,961, to which a response is due April 14, 2004. Accordingly, this RCE is timely filed.

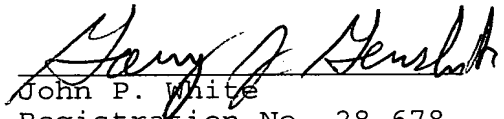
No fee, other than the RCE fee of \$385.00 and the fee of \$55.00 for a One-Month Extension of time, both enclosed on the check for \$440.00, is deemed necessary in connection with the filing of this Third Supplemental Information Disclosure Statement. If any such fee is required, authorization is hereby given to charge the amount


Applicant : Joseph R. Berger  
Serial No. : 10/052,961  
Filed : January 18, 2002  
Page 6

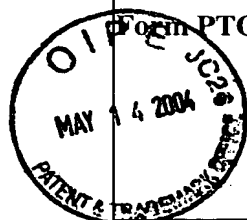
of any such fee to Deposit Account No. 03-3125.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Respectfully submitted,

  
John P. White  
Registration No. 28,678  
Gary J. Gershik  
Registration No. 39,992  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 44657-AAA-PCT-US		Serial No. 10/052,961						
 <p align="center"><b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)</p>				Applicant: Joseph R. Berger								
				Filing Date January 18, 2002		Group						
<b>U.S. PATENT DOCUMENTS</b>												
Examiner Initial		Document Number		Date	Name	Class	Filing Date if Appropriate					
	US	5	8	7	2	1	4	7	2/16/99	Bowen		
	US	6	5	7	6	6	5	9	6/10/03	Fishbein		
	US	6	6	7	0	3	5	1	12/30/03	Berger		
<b>FOREIGN PATENT DOCUMENTS</b>												
		Document Number		Date	Country	Class	Subclass	Translation				
								Yes	No			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>												
	U.S. Published Application No. 2002/0091155, Published July 11, 2002, Berger ( <b>Exhibit 4</b> );											
	U.S. Published Application No. 2003/0049716, Published March 13, 2003, Barton and Kramer. ( <b>Exhibit 5</b> );											
	U.S. Serial No. 10/799,264, filed March 12, 2004, Fishbein ( <b>Exhibit 6</b> );											
	U.S. Serial No. 10/799,197, filed March 12, 2004, Fishbein ( <b>Exhibit 7</b> );											
	Chicago Tribune, (Sep. 20, 1991), North Sports Final edition, Business Section, page 1 ( <b>Exhibit 8</b> );											
	Demling and DeSanti, (1997), "Oxandrolone, an Anabolic Steroid, Significantly Increases the Rate of Weight Gain In the Recovery Phase After Major Burns," <i>J. Trauma</i> , Vol. 43, No. 1, pp. 47-51 ( <b>Exhibit 9</b> );											
	Demling and De Santi, (October 1998), "Closure of the 'Non-Healing Wound' Corresponds with Correction of Weight Loss Using the Anabolic Agent Oxandrolone," <i>Ostomy/Wound Management</i> , Vol. 44, No. 10, pp. 58-60, 62, 64, 66, 68 ( <b>Exhibit 10</b> );											
	Demling, (1999), "Comparison of the Anabolic Effects and Complications of Human Growth Hormone and the Testosterone Analog, Oxandrolone, After Severe Burn Injury," <i>Burns</i> , Vol. 25, pp. 215-221 ( <b>Exhibit 11</b> );											
	Demling, (Mar-Apr 2000), "Oxandrolone, an Anabolic Steroid, Enhances the Healing of a Cutaneous Wound in the Rat," <i>Wound Repair Regen.</i> , Vol. 8, No. 2, pp. 97-102 ( <b>Exhibit 12</b> );											
	Demling and DeSanti, (2001), "The Rate of Restoration of Body Weight After Burn Injury, Using the Anabolic Agent Oxandrolone, is not Age Dependent," <i>Burns</i> , Vol. 17, pp. 46-51 ( <b>Exhibit 13</b> );											
	Demling and DeSanti, (September/October 2001), "The Anabolic Steroid, Oxandrolone, Reverses the Wound Healing Impairment in Corticosteroid-Dependent Burn and Wound Patients," <i>Wounds</i> , Vol. 13, No. 5, pp. 203-207 ( <b>Exhibit 14</b> );											
	DeSanti et al., (1998), "Development of a Burn Rehabilitation Unit: Impact on Burn Center Length of Stay and Functional Outcome," <i>Journal of Burn Care &amp; Rehabilitation</i> , Vol. 19, No. 5, pp. 414-419 ( <b>Exhibit 15</b> );											
	Ehrlich and Hunt, (August 1969), "The Effects of Cortisone and Anabolic Steroids on the Tensile Strength of Healing Wounds," <i>Ann Surg.</i> , Vol. 170, No. 2, pp. 203-206 ( <b>Exhibit 16</b> );											
	Eisenberg, (1966), 65 <i>Chemical Abstracts</i> :40387 ( <b>Exhibit 17</b> );											
	Eisenberg, (May 1966), "Effects of Androgens, Estrogens and Corticoids on Strontium Kinetics in Man," <i>J. Clin. Endocr.</i> , Vol. 26, pp. 566-572 ( <b>Exhibit 18</b> );											
	Ferraresi, (April 1996), "Clinical Profile of Oxandrin," BTG Pharmaceuticals ( <b>Exhibit 19</b> );											
	Grant, (1980), "Patient Selection," <i>Handbook of Total Parenteral Nutrition</i> , Saunders, pp. 7-46 ( <b>Exhibit 20</b> );											
EXAMINER				DATE CONSIDERED								
<p><b>*EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>												



Form PTO-1449

**U.S. Department of Commerce  
Patent and Trademark Office**

**Atty. Docket No.**

44657-AAA-PCT-US

**Serial No.**

10/052,961

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

**Applicant:**

Joseph R. Berger

**Filing Date**

January 18, 2002

**Group****U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

**FOREIGN PATENT DOCUMENTS**

Document Number	Date	Country	Class	Subclass	Translation
					Yes No

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Hausmann et al., (March/April 1990), "Anabolic Steroids In Polytrauma Patients. Influence on Renal Nitrogen and Amino Acid Losses: A Double Blind Study," <i>J. Parent. Enteral. Nutr.</i> , Vol. 14, No. 2, pp. 111-114 ( <b>Exhibit 21</b> );
	Helfman and Falanga, (August 1995), "Stanozolol as a Novel Therapeutic Agent in Dermatology," <i>J. of the American Acad. of Dermatology</i> , Vol. 33, No. 2, pp. 254-258 ( <b>Exhibit 22</b> );
	Jekot and Purdy, (April 1993), "Treating HIV/AIDS Patients with Anabolic Steroids," <i>AIDS Patient Care</i> , pp. 68-74 ( <b>Exhibit 23</b> );
	Koehler et al., (1998), "Achieving Healing of 'Non-Healing Pressure Ulcers," 1998 WOCN 30th Annual Conference, p. 37 ( <b>Exhibit 24</b> );
	Kotler, (1996), "Dilemmas in the Treatment of Weight Loss," BTG Pharmaceuticals, pp. 1-7 ( <b>Exhibit 25</b> );
	Levien et al., (July 1994), "Reviews of Trimetrexate and Oxandrolone," <i>Hospital Pharmacy</i> , Vol. 29, No. 7, pp. 696-702, 705-708 ( <b>Exhibit 26</b> );
	Martindale, (1982), <i>The Extra Pharmacopoeia 28<sup>th</sup> Edition</i> , The Pharmaceutical Press, London, Reynolds and Prasad Eds., p. 1430 ( <b>Exhibit 27</b> );
	PR Newswire, 0828P8715, (August 28, 1991), "Gynex Obtains International Rights to Drug to Treat For Growth Disorders, AIDS" ( <b>Exhibit 28</b> );
	Schwartz and Miller, (1986), "Androgens and Anabolic Steroids," in <i>Modern Pharmacology, Second Edition</i> , Little Brown and Company, Boston/Toronto, Craig and Stitzel Eds., pp. 905-924 ( <b>Exhibit 29</b> );
	Tennenbaum and Shklar, (December 1970), "The Effect of an Anabolic Steroid on the Healing of Experimental Extraction Wounds," <i>Oral Surg.</i> , Vol. 30, No. 6, pp. 824-834 ( <b>Exhibit 30</b> ); and
	Udapa and Chansouria, (March 1969), "Studies on Wound Healing," <i>Indian J. Med. Res.</i> , Vol. 57, pp. 434-456 ( <b>Exhibit 31</b> ).

**EXAMINER****DATE CONSIDERED**

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.